

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
1:25-cv-00368-TDS-JLW**

United Therapeutics Corporation,

Plaintiff,

v.

Liquidia Technologies, Inc.,

Defendant.

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANT LIQUIDIA
TECHNOLOGIES, INC.'S MOTION TO DISMISS OR, IN THE ALTERNATIVE,
STAY OR TRANSFER**

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INTRODUCTION

For five years now, UTC has (to date, unsuccessfully) used litigation to try to keep Liquidia's life-saving drug, Yutrepia, from serving patients suffering from pulmonary hypertension. This case is the third case alleging patent infringement and the seventh overall. Several doctrines—the first-filed rule, the rule against claim-splitting, issue and claim preclusion, and the *Kessler* doctrine—bar UTC from subjecting Liquidia to endless piecemeal litigation. This case should be dismissed.

ARGUMENT

I. Under the first-filed rule and the rule against claim-splitting, this case should be dismissed because it arises from the same essential transactional facts—Yutrepia's alleged infringement of UTC's patents for treatment of PH.

This case should be dismissed under the first-filed rule and the rule against claim-splitting. That is because this case and the currently pending *Hatch-Waxman II* litigation in Delaware arise from the same essential transactional facts—UTC's allegation that Liquidia's Yutrepia product infringes UTC's patents in connection with the treatment of PH. “[T]he policies underlying the res judicata doctrine” do not allow UTC to pursue piecemeal litigation—across multiple cases and jurisdictions—and put Liquidia “to the cost and vexation of multiple lawsuits, deplete judicial resources, foster inconsistent decision, and diminish reliance on judicial decisions.” *Sensormatic Sec. Corp. v. Sensormatic Elecs. Corp.*, 452 F. Supp. 2d 621, 628 (D. Md. 2006), *aff'd*, 273 F. App'x 256 (4th Cir. 2008); *see also SimpleAir v. Google, LLC*, 884 F.3d 1160, 1169 (Fed. Cir.

2018) (explaining claim preclusion). UTC’s various attempts to obscure the two cases’ factual similarities all fail, as follows.¹

A. UTC’s claims could have been brought in *Hatch-Waxman II*.

UTC’s response starts from a false premise—namely, that it could not have asserted claims about the ’782 Patent in *Hatch-Waxman II*. Specifically, UTC argues that it was precluded from raising the ’782 Patent in the pending case because it was not one of the patents listed in the FDA’s Orange Book for Tyvaso, the referenced drug at issue in *Hatch-Waxman II*, and thus does not fall within the Hatch-Waxman Act’s jurisdiction. (DE 56 at 8–10; *see also id.* at 10 (asserting that Delaware court “lacks jurisdiction” over ’782 patent claim)).

UTC is wrong. The Federal Circuit recognized long ago that non-Orange-Book-listed patents could be asserted in a Hatch-Waxman litigation like *Hatch-Waxman II*, where, as here, the claim was based on “imminent FDA approval” and threats of future infringement. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570–71 (Fed. Cir. 1997); *see also AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (holding that Orange Book listing is not a prerequisite to asserting a patent under § 271(e)(2), as jurisdiction arises once the patentee alleges that an FDA filing infringes its patent).

¹ Because UTC largely duplicates its arguments in response to the first-filed rule and the rule against claim splitting, Liquidia addresses the two doctrines together.

UTC has known that Liquidia intended to launch Yutrepia for the PAH indication since 2020 and for PH-ILD indication since July 2023. In addition, UTC filed *Hatch-Waxman II* in September 2023 and moved for a preliminary injunction in that case in February 2024 based on the argument that it would be imminently harmed when UTC's regulatory exclusivity was, at the time, set to expire in March 2024. As the Court has observed, “[b]ecause the ’782 patent issued in June 2022, UTC would have been aware of any potential infringement claim by then.” (DE 54 at 29). In addition, UTC “has not reconciled its earlier litigation contention that irreparable harm was sufficiently ‘imminent’ in February 2024” with any argument here that a declaratory judgment claim based on alleged infringement of the ’782 Patent would not have been ripe at that time. (*Id.*). Accordingly, under established Federal Circuit law, a declaratory judgment claim *could have been* brought in connection with the ’782 Patent in *Hatch-Waxman II*.

Indeed, this Court has already acknowledged Federal Circuit law in rejecting a similar argument from UTC in its order denying UTC's motion for preliminary injunctive relief. (DE 54 at 27–28). Not only does UTC ignore the Court's previous order, it cites no authority to the contrary. Instead, it re-raises two cases that the Court has already distinguished. DE 56 at 9 & n.2 (citing *Eisai Co., Ltd. v. Mut. Pharm. Co., Inc.*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007) and *Reckitt Benckiser Pharms., Inc. v. Biodelivery Scis. Int'l, Inc.*, 2014 WL 2119822 (E.D.N.C. May 20, 2014)). As the Court explained, *Reckitt* is “distinguishable” because, unlike here, there was no “evidence that the FDA had acted on the alleged infringer's NDA” and was thus too conjectural to support a declaratory

judgment claim. DE 54 at 29 n.12 (citing *Reckitt*, 2014 WL 2119822, at *2). And the Court explained that *Eisai* is “also distinguishable in part, as the parties stipulated that the alleged infringer would give the patentee 45 days’ written notice before ‘market[ing], offer[ing] to sell or sell[ing]’ a general product under its ANDA.” *Id.* (quoting *Eisai*, 2007 WL 4556958, at *7). UTC’s does not even attempt to address these issues in its response.

UTC also completely ignores that it is also alleging that Liquidia’s ongoing ASCENT clinical trial, which was begun in 2023, constitutes infringement of the ’782 patent. (DE 1, ¶ 36). This same ASCENT clinical trial also forms part of the basis for UTC’s claims of infringement in *Hatch-Waxman II*. Thus, even if UTC were correct that it lacked jurisdiction or standing under both Hatch-Waxman and for declaratory relief, it certainly had jurisdiction and standing based on its allegations of active and ongoing infringement in connection with the ASCENT clinical trial.

B. Claim-splitting is not limited to cases involving the same patent.

UTC also argues that claim-splitting cannot apply here because “infringement claims based on different patents do not satisfy the same transaction requirement.” DE 56 at 7 (citing *PPC Broadband, Inc. v. Corning Gilbert, Inc.*, 2013 WL 6145799, at *2 (N.D.N.Y. Nov. 21, 2013) and *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996)). That, too, is wrong.

In fact, the Federal Circuit has rejected that very argument, explaining that, “[w]hile ordinarily different patents will raise different causes of action, that factor is not dispositive and does not substitute for the transactional approach consistently followed by this court.”

SimpleAir, Inc. v. Google LLC, 884 F.3d 1160, 1166 (Fed. Cir. 2018) (cleaned up) (expressly rejecting UTC’s proposed rule). Instead, the Federal Circuit follows “general claim preclusion principles” to “determine[] pragmatically” “[w]hat factual grouping constitutes a ‘transaction.’” *Id.* The “rigid rule” advanced by UTC, on the other hand, “would prevent courts from evaluating the extent of factual overlap between cases.” *Id.*

C. UTC’s other attempts to distinguish the cases fail.

Applying that transactional approach, the factual overlap between this case and *Hatch-Waxman II* is undeniable. The parties are the same. The alleged infringing product is the same. The specifications and disclosures in ’793 Patent and the ’782 Patent are the same, and, as shown in Appendix A to Liquidia’s motion to dismiss (DE 29-1), the claims substantially overlap. (DE 29 at 7; *see also* DE 54 at 20 (commenting that “UTC rests its argument in favor of the ’782 patent’s validity on ... materially-similar claims in the ’793 patent.”)). And the alleged infringing conduct is identical. (DE 29 at 8–9). UTC was thus aware of Yutrepia’s alleged infringement of the ’782 patent when it filed its amended complaint in *Hatch-Waxman II* but elected not to assert that patent in that case. (DE 54 (UTC “would have been aware of any potential infringement claim” when the ’782 Patent issued in June 2022)).

In response, UTC repeatedly asserts that, because the two patents contain different claims, this case should be allowed to proceed. Yet the only distinction UTC identifies is the argument that, unlike the ’793 Patent, the “’782 Patent requires multiple doses at least

three hours apart” and that the ’782 Patent “includes a claim direct to the peak plasma concentration of drug in the blood.” (DE 56 at 14).

UTC misses the point. Like claim preclusion, claim-splitting prohibits parties from asserting claims that *could have been* brought in the first litigation. *In re Varat Enters., Inc.*, 81 F.3d 1310, 1315 (4th Cir. 1996) (“Rules of claim preclusion provide that if the later litigation arises from the same cause of action as the first, then the judgment bars litigation not only of every matter actually adjudicated in the earlier case, but also of every claim that might have been presented.”). Thus, even if there are minor distinctions between the claims in the two patents, the rule against claim-splitting prohibits UTC from separating its suits about the same product’s same alleged infringement of two largely overlapping patents across multiple cases and jurisdictions. Aside from its misguided argument that the Delaware court lacked jurisdiction over claims related to the ’782 Patent, UTC provides no reason why it could not have included three-hour interval or plasma concentration theories of infringement before.

UTC provides no reason because it has none. UTC has known Yutrepia’s prescribed dosing interval since, at least, 2022. (DE 29 at 9 (explaining that Yutrepia’s dosing interval was disclosed on the 2021 Label and Instructions for Use, which was a trial exhibit in *Hatch-Waxman I*)). As for “peak plasma concentration,” UTC has not even alleged that patent claim as a theory of infringement *in this case*. As this Court has already mentioned, only claim 1 of the ’782 Patent was “specifically alleged” in the complaint. DE 54 at 11 (citing DE 1 ¶¶ 46–47). Claims about plasma concentration appear in claim 8 of ’782

Patent. Neither claim 8 nor the words “plasma concentration” appear anywhere in UTC’s complaint. UTC cannot rely on an unpleaded theory of infringement to save its case.²

To be sure, as UTC points out, some courts have exercised their discretion to allow later-filed cases to proceed despite overlapping parties, products, and patents. (DE 56 at 13–14). Their reasons for doing so, however, are not present here. *See, e.g., Netlist Inc. v. SK Hynix Inc.*, 2021 WL 2954095, at *3 (W.D. Tex. Feb. 2, 2021) (exercising discretion to refuse to transfer second-filed case because, in part, that case, unlike here, involved an unrelated patent); *Abbott Lab’ys v. Johnson and Johnson, Inc.*, 524 F. Supp. 2d 553, 558 (D. Del. 2007) (doing same where, unlike here, patent in the second-filed case “did not exist” when the first case was filed); *APV N. Am., Inc. v. Sig Simonazzi N. Am., Inc.*, 295 F. Supp. 2d 393, 398 (D. Del. 2002) (doing same where, unlike here, the relevant inventions “involve different technologies and thus, different facts”).

Courts facing circumstances such as these, on the other hand, routinely apply the rule against claim-splitting to dismiss claims because they involve the same transactional facts. *See, e.g., Finjan, Inc. v. Blue Coat Sys., LLC*, 230 F. Supp. 3d 1097, 1102–03 (N.D.

² UTC also argues that, because this case concerns both the PAH and PH-ILD indications and because *Hatch-Waxman II* only concerns PH-ILD, different evidence would have been needed to litigate the ’782 Patent in Delaware. (DE 56 at 15–16). In making that argument, UTC ignores that the ’793 patent, which was included in *Hatch-Waxman II*, concerns both the PAH and PH-ILD indications. Moreover, UTC effectively concedes that the same evidence would apply for the PH-ILD indication anyway. UTC does not identify any new evidence that would be needed, much less how it would be any different than the evidence introduced in *Hatch-Waxman I*, which concerned both PAH and the ’793 Patent and which bars this case on other preclusion grounds. (See DE 23 at 16–23). Similar issues also foreclose UTC’s (incorrect) argument that Liquidia relies on *Hatch-Waxman I* for its first-filed arguments. (DE 56 at 11–12).

Cal. 2017) (applying the doctrine prohibiting claim-splitting where the allegedly infringing products are the same or substantially the same and where patents could have been asserted in first case and citing cases holding same); *Xidrone Sys., Inc. v. Fortem Techs., Inc.*, 2024 WL 4452708, at *4–5 (D. Utah Oct. 9, 2024) (same); *see also MAZ Encryption Techs., Inc., LLC v. Blackberry Ltd.*, 347 F. Supp. 3d 283, 290–91 (N.D. Tex. 2018) (holding that claim preclusion barred third suit based on different, but materially similar, patents and the same allegedly infringing devices). This Court should do the same and dismiss this case as barred by the first-filed rule and the rule against claim-splitting.

II. UTC’s claims should be dismissed because they are barred by claim preclusion, issue preclusion, and the *Kessler* doctrine as the claims raised here should have been litigated and the issues were litigated in Delaware.

A. Claim preclusion applies here for the same reasons the doctrine against claim-splitting applies.

For essentially the same reasons that the doctrine against claim-splitting bars UTC’s claims, claim preclusion also applies, because UTC seeks to relitigate matters ended by final judgment in *Hatch-Waxman I* and dismissal of claims related to the ’793 Patent in *Hatch-Waxman II*. In response, UTC generally raises the same arguments already addressed above—namely, the incorrect assertions that it could not have raised the ’782 Patent in Delaware, that claim preclusion only applies to identical patents, and that the cases do not arise from the same transactional facts. DE 56 at 17–20. These arguments fail for the same reasons that they fail in connection with claim-splitting.

Indeed, UTC even acknowledges (albeit in passing) the Federal Circuit’s holding in *SimpleAir* that claim preclusion *does* apply to cases involving different patents. DE 56 at

19. UTC tries to distinguish the case, however, asserting that the patents at issue there had a “terminal disclaimer” (under which a patentee limits the term of a patent to avoid obviousness concerns), while there is “no terminal disclaimer here.” *Id.*

UTC misreads *SimpleAir*. There, directly contrary to UTC’s reading of the case, the Federal Circuit reversed the district court’s claim preclusion decision *because* the district court relied almost solely on the terminal disclaimer in determining that the patents were materially similar. *SimpleAir*, 884 F.3d at 1169 (holding that “a district court cannot presume that a terminally-disclaimed continuation patent presents the same cause of action as a parent patent based on the filing of the terminal disclaimer alone”). Instead, the Federal Circuit explained, “the claim preclusion analysis requires comparing the patents’ claims along with other relevant transactional facts.” *Id.* at 1168. The Federal Circuit remanded the case for the district court to perform the proper analysis. Accordingly, the absence of a terminal disclaimer here is irrelevant, and, under the proper transactional-facts analysis, claim preclusion bars this case.

B. Issue preclusion also bars UTC’s case.

Because UTC has already had a full and fair opportunity to litigate the issues raised here when it fully litigated the validity of ’793 Patent in Delaware, issue preclusion bars UTC from relitigating those issues here. (DE 29 at 18–21). In response, UTC once again focuses on alleged differences between the ’793 Patent’s and the ’782 Patent’s claims, arguing that Liquidia has failed to show that the patents are identical.

But the Federal Circuit has said that its “precedent does not limit collateral estoppel to patent claims that are identical.” *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013); *see also Allergan, Inc. v. Apotex, Inc.*, 2015 WL 13358250, at *2 (M.D.N.C. Aug. 31, 2015), *aff’d sub nom. Allergan, Inc. v. Sandoz, Inc.*, 68 F. App’x 955 (Fed. Cir. 2017). “Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply.” *Ohio Willow Wood*, 735 F.3d at 1342. And UTC has litigated the issue of Yutrepia’s infringement to final judgment, including issues involving device, dosage, and administration. (DE 29 at 8–9 (detailing the issues litigated in *Hatch-Waxman I*)). And the substantial similarity between the ’793 Patent and the ’782 Patent shows that any alleged differences “do not materially alter the question of invalidity.” *Ohio Willow Wood*, 735 F.3d at 1342; *see also* DE 29-1 (chart comparing ’793 Patents claims with ’782 Patent’s claims); DE 54 at 15–17 (recounting similarities between the two patents’ claims and their respective questions of invalidity).

UTC’s remaining arguments are unpersuasive. UTC’s only ground for distinguishing *Allergan* appears to be that the defendant in that case presented a color-coded chart comparing the patents at issue. (DE 56 at 20–21). UTC thus fails to respond to Liquidia’s lengthy discussion of that case and its similarities to the facts here. (DE 29 at 20–21). And UTC’s sole ground for distinguishing *Ohio Willow Wood* is that the case involved summary judgment, rather than a motion to dismiss. (DE 56 at 21). But that is no response to Liquidia’s basis for relying on the case—that, under Federal Circuit law, collateral estoppel is not limited to identical patents. And, of course, that precedent renders

UTC's conclusory assertion that "different patents mean different issues" wrong as a matter of law. (DE 56 at 21).

C. The *Kessler* doctrine also bars UTC's case.

The *Kessler* doctrine precludes UTC from doing exactly what is trying to do here—subjecting Liquidia's noninfringing product, Yutrepia, to serial patent litigation. (DE 29 at 21–23). In response, UTC argues, once more, that the doctrine does not apply to different patents. (DE 56 at 22). Once more, however, UTC is wrong. Indeed, UTC acknowledges that in *SimpleAir*, the Federal Circuit held otherwise. (*Id.* (citing *SimpleAir, Inc.* and conceding that it "involves different patents")). Nor is there any merit to UTC's repeated assertion that the "terminal disclaimer" distinguishes these cases. (*Id.*). The language that UTC quotes in its brief comes from the Federal Circuit's discussion of claim preclusion, not the *Kessler* doctrine. (*Id.* (quoting *SimpleAir*, 884 F.3d at 1168)). In any event, because the claims of the '793 Patent and the '782 Patent are materially similar, the *Kessler* doctrine also bars UTC's case. *See SimpleAir*, 884 F.3d at 1170.

CONCLUSION

Because multiple doctrines preclude UTC from subjecting Liquidia to endless litigation over the same issues concerning the same product, Liquidia requests that the Court dismiss this case.

This the 20th day of June, 2025.

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CERTIFICATION OF COMPLIANCE

Pursuant to Local Rule 7.3(d)(1), the undersigned hereby certifies that this brief contains no more than 3,125 words, as calculated by the word count feature of Microsoft Word, Office 365 ProPlus.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was electronically filed with the Clerk of the Court by using the CM/ECF System which will automatically send notice of the same addressed to all counsel of record.

This the 20th day of June, 2025.

/s/ Stephen V. Carey
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